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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,305	10/05/2004	Britta Evers	X-15722	2438
25885	7590	10/02/2007		
ELI LILLY & COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			EXAMINER STOCKTON, LAURA LYNNE	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 10/02/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

## Office Action Summary

Application No.

10/510,305

Applicant(s)

EVERS ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on July 30, 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 37-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 and 37-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

Claims 1-34 and 37-74 are pending in the application.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 30, 2007 has been entered.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicant's

amendments to the claims. Therefore, arguments pertaining to these rejections will not be addressed.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-34 and 37-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 and 23-25 of copending Application No. 10/510,393.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed invention is generically claimed in the copending application. See, for instance, the species of claim 25 in copending Application No. 10/510,393.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., modulation of endogenous growth hormone levels).

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One skilled in the art would thus be motivated to prepare products embraced by the copending application to arrive at the instant claimed products with the expectation of obtaining additional beneficial products that would modulate endogenous growth hormone levels. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicant's arguments filed July 30, 2007 have been fully considered. Applicant states that a Terminal Disclaimer will be submitted in this application when all other issues have been resolved.

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Claims 1, 2, 6, 7, 22-32, 37, 38 and 45-50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent No. 7,125,840 (matured from application 10/380,867). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed invention is generically claimed in each of the copending applications. See Example 13 in column 37 of the patent.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., modulation of endogenous growth hormone levels).

One skilled in the art would thus be motivated to prepare products embraced by the patent to arrive at the instant claimed products with the expectation of

obtaining additional beneficial products that would modulate endogenous growth hormone levels. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

### ***Response to Arguments***

Applicant's arguments filed July 30, 2007 have been fully considered but they are not persuasive.

Applicant argues that the provisos in the currently amended claims circumvent the subject matter embraced by the claims in the patent.

Applicant's arguments have been considered but have not been found persuasive. Currently amended claims circumvent do not circumvent the claims in Dodge et al. See Example 13 in the patent (reproduced below).



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RN 416854-16-5 CAPLUS

CN D-Serinamide, 2-methylalanyl-N-[[3-(4-chlorophenyl)-2,2-dioxido-2-thia-1-azaspiro[4.5]dec-3-en-4-yl)methyl]-N,O-bis(phenylmethyl)-, mono(trifluoroacetate) (9CI) (CA INDEX NAME)

CM 1

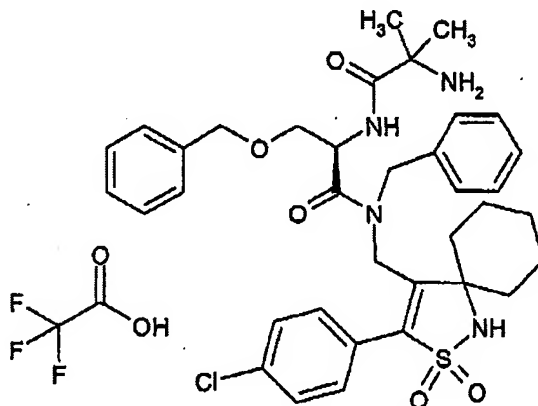
CRN 416854-15-4

CMF C36 H43 Cl N4 O5 S

Absolute stereochemistry.

## EXAMPLE 13

2-(R)-2-(2-Amino-2-methylpropionylamino)-3-phenylmethoxy-  
propionic acid N-benzyl-N-(3-(4-chlorophenyl)-2,2-dioxo-2-  
thia-1-azaspiro[4.5]dec-3-ene-4-ylmethyl) amide  
trifluoroacetate



Example 13 of Dodge et al. is embraced by the claims in the Dodge et al. patent and the currently amended claims as follows:

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R1 is an unsubstituted C<sub>1</sub>-C<sub>6</sub>alkyl-NHR10 wherein R10 is hydrogen; R2 is hydrogen; R3 is unsubstituted C<sub>1</sub>-C<sub>6</sub>alkyl-(O)-C<sub>1</sub>-C<sub>6</sub>alkylaryl; R4 is hydrogen; R5 is a substituted C<sub>1</sub>-C<sub>6</sub>alkyl; m is one; R6 and R7 together with the carbon atom to which they are attached form a carbocyclic ring of up to 8 atoms (i.e., cyclohexyl); R8 is hydrogen; R9 is a substituted aryl; Q is -S(O)<sub>2</sub>-. Note the second proviso at the end of instant claim 1. The rejection is deemed proper and therefore, the rejection is maintained.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

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particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 43, it is not clear what is meant by the phrase "A method c thereof".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6, 7, 22-32, 37, 38 and 45-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Dodge et al. {WO 2002/32888}.

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Dodge et al. disclose Example 13 {CA Registry No. 416854-16-5} on page 70 that is embraced by the instant claimed invention. Therefore, Dodge et al. anticipates the instant claimed invention.

### ***Response to Arguments***

Applicant's arguments filed July 30, 2007 have been fully considered but they are not persuasive.

Applicant argues that the currently amended claims circumvent the disclosure in Dodge et al. In response, the currently amended claims circumvent all of the species in Dodge et al. except one, that being Example 13 (reproduced below).

RN 416854-16-5 CAPLUS  
CN D-Serinamide, 2-methylalanyl-N-[[3-(4-chlorophenyl)-2,2-dioxido-2-thia-1-azaspiro[4.5]dec-3-en-4-yl)methyl]-N,O-bis(phenylmethyl)-, mono(trifluoroacetate) (9CI) (CA INDEX NAME)

CM 1

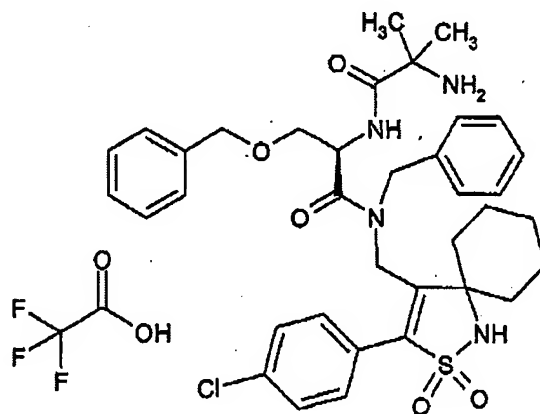
CRN 416854-15-4  
CMF C36 H43 Cl N4 O5 S

Absolute stereochemistry.

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## EXAMPLE 13

2-(R)-2-(2-Amino-2-methylpropionylamino)-3-phenylmethoxy-  
propionic acid N-benzyl-N-(3-(4-chlorophenyl)-2,2-dioxo-2-  
thia-1-azaspiro[4.5]dec-3-ene-4-ylmethyl) amide  
trifluoroacetate



Example 13 of Dodge et al. is embraced by the currently amended claims as follows:

R1 is an unsubstituted C<sub>1</sub>-C<sub>6</sub>alkyl-NHR<sub>10</sub> wherein R<sub>10</sub> is hydrogen; R2 is hydrogen; R3 is unsubstituted C<sub>1</sub>-C<sub>6</sub>alkyl-(O)-C<sub>1</sub>-C<sub>6</sub>alkylaryl; R4 is hydrogen; R5 is a substituted C<sub>1</sub>-C<sub>6</sub>alkyl; m is one; R6 and R7 together with the carbon atom to which they are attached form a carbocyclic ring of up to 8 atoms (i.e., cyclohexyl);

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R8 is hydrogen; R9 is a substituted aryl; Q is  $-S(O)_2-$ .

Note the second proviso at the end of instant claim 1.

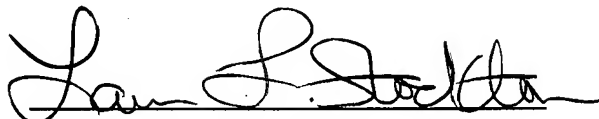
Therefore, the rejection is deemed proper and is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read 'Laura L. Stockton', written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

September 27, 2007